

II. REMARKS

A. Status of the Claims

Claims 1 to 35 and 64 to 84 are pending. Claims 36 to 63 were cancelled without prejudice in response to the Restriction Requirement dated May 28, 2009. It is respectfully submitted that no new matter was added in this amendment.

B. Rejection under 35 U.S.C. § 102 in view of U.S. Patent No. 5,533,502 to Piper

In the office action, the Examiner rejected claims 1-5, 8-13, 28-30, 31, 64, and 72 under 35 U.S.C. §102(b) as being anticipated by Piper (U.S. Patent No. 5,533,502). The Examiner stated:

'Piper discloses an inhaler comprising a housing to receive a plurality of blisters each having a puncturable lid and containing a dose of a medicament for inhalation..., a mouthpiece (52) through which medicament is inhaled and acts an arm of pivotally mounted actuator that sequentially moves each blister into alignment with a blister piercing member..., due to the blister being pivoted into position by the actuator the lid of a blister is caused to be pierced by the blister piercing member such that airflow through the blister entrains a dose of medicament to be inhaled...."

Applicants respectfully traverse this rejection. To anticipate a claim, the reference must teach every element of the claim (See: MPEP, section 2131.01). Independent claim 1 of the present invention recites:

Claim 1. An inhaler comprising a housing to receive a plurality of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, a mouthpiece through which a dose of medicament is inhaled by a user and *an actuator pivotally mounted to the housing, said actuator being pivotable to sequentially move each blister into alignment with a blister piercing member, said actuator also being pivotable to cause the blister piercing member to puncture the lid of an aligned blister* such that, when a user inhales through the mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it via the mouthpiece into the user's airway.

Applicants respectfully submit that the fundamental difference between the device as claimed in independent claim 1 of the present application and the device described in the Piper reference is that the actuator of the device of the present invention is "pivotally mounted to the housing" and is also "pivotable" to cause the blister piercing member to puncture the lid of an

aligned blister. In other words, the same actuator is pivoted to perform the function of both indexing and piercing.

In contrast, the "actuator" described in the Piper reference is represented by the carriage 24. The carriage is first rotated to a position to align one of the medicament receptacles for dispensing ("indexing") (See: Piper, col. 2, lines 56-58). Then, the carriage and cover must be *depressed, not pivoted*, in order to pierce.

Furthermore, in the office action, the previous examiner seems to have made the incorrect presumption that the mouthpiece 52 of Piper "acts as an arm of a pivotally mounted actuator" (See: Office Action, page 2, paragraph 4). This statement is inaccurate as the housing is stationary and it is only the carriage 24, within the housing, that is actually rotated by a patient. Even then, this is not the same as the presently claimed invention ("*an actuator pivotally mounted to the housing, said actuator being pivotable to sequentially move each blister into alignment with a blister piercing member, said actuator also being pivotable to cause the blister piercing member to puncture the lid of an aligned blister*")

In view of the above arguments, it is apparent that the Piper reference does not teach each and every element of independent claim 1. Accordingly, independent claim 1 and claims 2-5, 8-13, 28-30, 31, 64, and 72 that depend therefrom are not anticipated by the Piper reference. Therefore, Applicants respectfully request that the Examiner's rejection be removed.

C. Rejection under 35 U.S.C. § 102 in view of U.S. Patent No. 6,880,555) to Brunnberg

In the office action, the Examiner rejected claims 1, 14-16, 18-20, 32-35, 71, and 73 to 83 under 35 U.S.C. §102(e) as being anticipated by Brunnberg (U.S. Patent No. 6,880,555). The Examiner stated:

'Brunnberg discloses an inhaler comprising a housing to receive a plurality of blisters...with puncturable lids containing doses of medicament for inhalation and an actuator that pivots about an axis...that acts as an indexing mechanism that

moves a blister alignment with a blister piercing member with an indexing wheel...
and causes the lids to be pierced to generate an airflow through the blister to entrain....'

Applicants respectfully traverse this rejection. As previously presented in the response submitted on February 3, 2010, the inhaler disclosed in Brunnberg is breath actuated, i.e. a blister is pierced in response to a user inhaling through a mouthpiece, rather than in response to operation of an actuator. Unlike independent claim 1 of the present invention which recites that the "*actuator also being pivotable to cause the blister piercing member to puncture the lid of an aligned blister*", the device described in the Brunnberg reference clearly requires a further action (namely patient inhalation) in order to pierce the blister.

Furthermore, Applicants respectfully submit that it is clear from the language of claim 1 of the present application that the actuator of the present invention is NOT operable in response to inhalation by a user because the claim clearly recites that the operations of the actuator are "*such that, when the user inhales through the mouthpiece, an airflow is generated to entrain the dose and carry it via the mouthpiece into the users airway*" thereby making it clear that a user inhales through the mouthpiece only subsequent to operation of the actuator to align and pierce a blister. Therefore, operation of the actuator must be achieved by something other than by inhalation.

Therefore, Brunnberg does not show or teach "An inhaler comprising a housing to receive a plurality of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, a mouthpiece through which a dose of medicament is inhaled by a user and an actuator pivotally mounted to the housing, said actuator being pivotable to sequentially move each blister into alignment with a blister piercing member, said actuator also being pivotable to cause the blister piercing member to puncture the lid of an aligned blister such that, **when a user inhales through the mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it via the mouthpiece into the user's airway**" as recited in claim 1 of the present invention.

Independent claim 73 of the present application recites that the actuator is “*operable, in response to rotation of the cap, to cause the blister piercing member to puncture the lid of an aligned blister*”. However, in Brunnberg, it is inhalation through the mouthpiece which causes the piercing elements to pierce the lid of an aligned blister rather than movement of the protective cover 236. The protective cover 236 fulfills the function of an actuator only to the extent that it comprises a toothed wheel 242 that engages the surface of a blister cartridge and causes it to rotate so as to align a fresh blister with the piercing members formed by elongate body 208 when the protective cover is closed. Although the protective cover 236 has a tongue 238 that engages a holding member 228 when the protective cover 236 is closed, it should be noted that even without the tongue 238, the holding member 228 is prevented from sliding under the bias provided by the pressure spring 226 due to arm 234 that has a ledge that engages with a corresponding ledge on the holding member 228 (see Brunnberg, column 9, lines 7 to 26). The ledge of the arm 234 only moves out of engagement with the ledge of the holding member 228 in response to a pressure difference between the interior and exterior of the inhaler, caused by inhalation. Once disengaged, the holding member 228 is then free to slide forwards under the force of the pressure spring 226 (see Brunnberg, column 9, lines 26 to 39).

Therefore, Brunnberg does not teach “An inhaler comprising a housing to receive a plurality of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, a mouthpiece through which a dose of medicament is inhaled by a user, an actuator and, a cap coupled to the actuator, the cap being rotatable to sequentially move each blister into alignment with a blister piercing member, said actuator being **operable, in response to rotation of the cap, to cause the blister piercing member to puncture the lid of an aligned blister** such that, when a user inhales through the mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it out of the blister and via the mouthpiece into the user’s airway” as recited in claim 73 of the present invention.

In view of the foregoing, Applicants respectfully submit that the Brunnberg reference does not teach each and every element of the presently claimed invention. Accordingly independent claim 1 and 73 and the claims that depend therefrom are not anticipated by the

Brunnberg reference. Therefore, Applicants respectfully request that the Examiner's rejection be removed.

D. Rejection under 35 U.S.C. § 103 in view of Piper (U.S. Patent No. 5,533,502)

In the Office Action, claims 6 and 7 were rejected under 35 U.S.C. §103(a) as being unpatentable over Piper (U.S. Patent No. 5,533,502).

Claims 6 and 7 indirectly depend from claim 1.

As noted above, Applicants respectfully submit that claim 1, as amended, recites that the actuator is "pivotally mounted to the housing" and also to specify that the actuator is "pivotable" to cause the blister piercing member to puncture the lid of an aligned blister.

Although Piper discloses an actuator (carriage 24), it is only pivotable to enable each blister to be moved into alignment with a blister piercing member and does not pivot in order to pierce an aligned blister. On the contrary, in the device disclosed in Piper, the user must depress the carriage 24 in relation to the cover 12 so that the inlet and outlet conduits puncture the seal of an aligned medicament receptacle, as shown in Figures 3 and 4 and described at column 5, lines 66-67. Notably, compression of the carriage 24 actually ensures rotation of the carriage is prevented because registration keys 46 engage with registration gear 28, as stated at column 6, lines 2 to 5.

Piper does not teach or suggest "an actuator pivotally mounted to the housing, said actuator being pivotable to sequentially move each blister into alignment with a blister piercing member, said actuator also being pivotable to cause the blister piercing member to puncture the lid of an aligned blister" as recited in amended claim 1 of the present invention. Therefore, the inhaler as recited in claim 1 of the present invention is not obvious over Piper (U.S. Patent No. 5,533,502).

For the foregoing reasons, Applicants submit that Piper (U.S. Patent No. 5,533,502) does not teach or suggest, or otherwise make obvious, the claimed inhaler recited in claims 6 and 7. Accordingly, the rejection of claims 6 and 7 under 35 USC 103(a) citing Piper (U.S. Patent No. 5,533,502) is respectfully requested to be withdrawn.

E. Rejection under 35 U.S.C. § 103 in view of Brunnberg (U.S. Patent No. 6,880,555)

In the Office Action, claims 17, 76, 78, 80, 82, and 83 were rejected under 35 U.S.C. §103(a) as being unpatentable over Brunnberg (U.S. Patent No. 6,880,555).

As noted above, Applicants respectfully submit that the inhaler disclosed in Brunnberg is breath actuated, i.e. a blister is pierced in response to a user inhaling through a mouthpiece, rather than in response to operation of an actuator. Applicants respectfully submit that it is clear from the language of claim 1 of the present invention that the actuator of the present invention is NOT operable in response to inhalation by a user because the claim clearly recites that the operations of the actuator are “*such that, when the user inhales through the mouthpiece, an airflow is generated to entrain the dose and carry it via the mouthpiece into the users airway*” thereby making it clear that a user inhales through the mouthpiece only subsequent to operation of the actuator to align and pierce a blister. Therefore, operation of the actuator must be achieved by something other than by inhalation.

Therefore, Brunnberg does not teach or suggest “An inhaler comprising a housing to receive a plurality of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, a mouthpiece through which a dose of medicament is inhaled by a user and an actuator pivotally mounted to the housing, said actuator being pivotable to sequentially move each blister into alignment with a blister piercing member, said actuator also being pivotable to cause the blister piercing member to puncture the lid of an aligned blister such that, **when a user inhales through the mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it via the mouthpiece into the user's airway**” as recited in claim 1 of the present invention.

For the foregoing reasons, Applicants submit that Brunnberg (U.S. Patent No. 6,880,555) does not teach or suggest, or otherwise make obvious, the claimed inhaler recited in claims 17, 76, 78, 80, 82, and 83. Accordingly, the rejection of claims 17, 76, 78, 80, 82, and 83 under 35 USC 103(a) citing Brunnberg (U.S. Patent No. 6,880,555) is respectfully requested to be withdrawn.

F. Rejection under 35 U.S.C. § 103 in view of Brunnberg (U.S. Patent No. 6,880,555) in further view of Widerstrom (U.S. 6,698,425)

In the office action, the Examiner rejected claims 21-27 and 84 under 35 U.S.C. § 103(a) as being unpatentable over Brunnberg as applied to claim 1 above, and in further view of Widerstrom.

Applicants reiterate the arguments presented above in connection with the Brunnberg reference.

Claim 1 of the present invention requires that the actuator is operable to "*sequentially move each blister into alignment with a blister piercing member, said actuator also being pivotable to cause the blister piercing member to puncture the lid of an aligned blister*". Although Widerstrom discloses an actuator (opening means 16), there is no explicit teaching or suggestion that movement of the opening means 16 also sequentially moves each blister into alignment with a blister piercing member. It is noted that column 6, lines 7 and 8 refers to the roll as being "automatically unwound and advanced through the inhaler" and column 6, lines 30 and 31 refers to advancement that can "easily be achieved by a mechanical ratchet arrangement". However, there is nothing to indicate that this advancement is achieved as a result of operating the opening means 16. Indeed, we consider that reference to the roll as being "automatically unwound" would lead a skilled person away from the invention, as it implies that the roll unwinds without any need for a user to manually operate an actuator for this purpose.

Applicants respectfully submit that the present invention as recited in amended claim 1 is further distinguished from the disclosure in Widerstrom because the opening means 16 are slideably mounted within the device housing rather than pivotally mounted, as required by amended claim 1 of the present invention.

Therefore, Widerstrom does not teach or suggest “An inhaler comprising a housing to receive a plurality of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, a mouthpiece through which a dose of medicament is inhaled by a user and an actuator pivotally mounted to the housing, said actuator being pivotable to **sequentially move each blister into alignment with a blister piercing member, said actuator also being pivotable to cause the blister piercing member to puncture the lid of an aligned blister** such that, when a user inhales through the mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it via the mouthpiece into the user’s airway” as recited in claim 1 of the present invention.

Accordingly, since claims 21-27 and 84 depend from independent claim 1, these claims are not obvious over the Brunnberg reference in further view of the Widerstrom reference. Therefore, Applicants respectfully request that the Examiner’s rejection be removed.

Conclusion

An early and favorable action on the merits is earnestly requested.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

/Richard V. Zanzalari/

By: _____

Richard V. Zanzalari
Reg. No. 49,032

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940